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EXAMINER	
SASAN, ARADHANA	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/758,233	BERTELSEN ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68,70-72,75-80,82,83,85-109 and 111-122* is/are pending in the application.

4a) Of the above claim(s) *97-107 and 112-114* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68, 70-72, 75-80, 82-83, 85-96, 108-109, 111 and 115-122* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks, amendments, Request for Continued Examination filed on 09/15/08 are acknowledged.

2. Claims 97-107 and 112-114 were withdrawn. New claims 115-122 were added.

3. Claims 68, 70-72, 75-80, 82-83, 85-96, 108-109, 111 and 115-122 are included in the prosecution.

Continued Examination under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/15/08 has been entered.

Response to Arguments

Provisional rejection of claims 68, 70-72, 75-80, 82-83, 85-96, and 108-111 under nonstatutory obviousness type double patenting

5. In light of Applicant's filing of a terminal disclaimer (09/15/08) and the approval of the terminal disclaimer (10/28/08), the nonstatutory obviousness type double patenting rejection is withdrawn.

Rejection of claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96 and 108-111 under 35 USC § 103(a)

6. Applicant's arguments, see Pages 11-20, filed 09/15/08, with respect to the rejection of claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96 and 108-111 under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) have been fully considered.

Applicant argues (see Page 12) that no reference has been provided by the Examiner to demonstrate that one of skill in the art would recognize particle size as a "result effective variable". Applicant requests that the Examiner provide a reference related to formulation of pharmaceutical compositions for tableting or filling of capsules demonstrating that one of skill in the art would expect that the use of granules of the claimed size would result in a pharmaceutical composition appropriate for tableting.

Applicant provided selected pages from Remington's Pharmaceutical Sciences, 16th Edition (1980) and argues that (see Page 14) the indication that mesh size should be selected based on the size tablets to be prepared demonstrates that one of skill in the art did not, and still does not, consider granulation particle size to be a "result effective variable."

Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) teach that drug particle size is a characteristic that influences dissolution from tablets and capsules (Page 515). Melia teaches that "increasing the available surface area by reducing the particle size can often markedly improve dissolution rates and lead to dramatic improvements in bioavailability" (Page 515, 1st full paragraph, under the heading "Drug particle size"). Therefore, one of ordinary skill in the art would know that by modifying the drug particle size, i.e. by reducing the drug particle size, the surface area is

increased and consequently, the dissolution rate is increased, which further leads to improved bioavailability.

Klioze et al. (US 2,887,439) teach a tablet that may be swallowed whole, chewed, dissolved in the mouth, or dissolved or suspended in liquids (Col. 2, lines 6-12). This rapidly disintegrating tablet comprises a plurality of compressed granules containing sweetening agents and perhaps a filler (Col. 2, lines 13-20). The granules used in the tablets are screened "to insure that they are of an optimum size for the formation of tablets. It has been found that granules ranging from about 20 to 100 mesh (U.S. Sieve Series) are most advantageous in preparing the tablets of this invention" (Col. 2, lines 41-46). 20 mesh corresponds to 0.84mm or 840μm and 100 mesh corresponds to 0.149mm or 149μm (see Page 1544 of Remington's 16th Edition 1980, as provided by Applicant on 09/15/08). Therefore, Klioze teaches the formation of rapidly disintegrating tablets comprising granules that are between 149μm and 840μm, thereby rendering the instant claims with the limitation of the mean particle size of the particles of the particulate composition at the most 250μm obvious to one of ordinary skill in the art.

Bhardwaj et al. (US 5,578,316) teach a pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns (Col. 6, claim 1, lines 11-24). A chewable tablet containing the pharmaceutical granule composition is also disclosed (Col. 6, claim 5, lines 35-37). Therefore, one of ordinary skill in the art would know that an orally administrable tablet composition that releases the active rapidly (a chewable tablet that disintegrates in the

mouth will rapidly release the granules that are in the tablet) can be produced by using a granule composition where the final particle size of the granule is from about 200 to about 400 microns. The particle size range of the granule taught by Bhardwaj renders the instant claims with the limitation of the mean particle size of the particles of the particulate composition at the most 250μm obvious to one of ordinary skill in the art.

Applicant notes that in the 10 formulations taught by Nemoto, there is no teaching or suggestion to modify the method of making granules for the preparation of tablets or capsules and the claimed invention is not a “predictable variation” of the teachings of Nemoto.

This is not persuasive because one of ordinary skill in the art would use granules comprising active ingredients such as oxicams and antacid in an orally administrable tablet formulation, as suggested by Nemoto, and use the particle size of about 200 to about 400 microns, as evidenced by Bhardwaj, and produce the instant invention. One of ordinary skill in the art would do this because Bhardwaj teaches that a pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns can be incorporated into a chewable tablet (Col. 6, claim 1, lines 11-24 and claim 5, lines 35-37).

Applicant submits that there would be no motivation to modify the methods of Nemoto as they do not provide a problem to be solved. The Advisory Action disagrees with this assertion noting that "Nemoto states that the "rapid action of anti-inflammatory drugs is remarkably improved" (Page 4), thereby showing the problem to be solved. Applicant asserts that Nemoto solves the problem that was noted by Nemoto in the prior

art. Nemoto "remarkably improved' the properties of the agents. No problem remains. Applicant states that there must be some motivation to modify the cited art to make an obviousness rejection. Applicant argues (see Page 16) that there can be no "rational underpinning" to modify the teachings of a reference that provides a composition that has all of the desired characteristics, as in Nemoto. Applicant argues that there is no room for “improvement” of Nemoto, it is already 100% efficient at the earliest time point tested, and it cannot be made faster or more efficient. Applicant argues that Nemoto neither teaches nor suggests that varying the method for tablet preparation could alter dissolution properties, or how one might alter methods of tablet preparation to alter dissolution properties.

This is not persuasive because one of ordinary skill in the art would know that by reducing the particle size of a granulation, the surface area of the granule can be increased, which consequently leads to a faster dissolution rate. This is evidenced by (Page 515, 1st full paragraph, under the heading “Drug particle size”). Nemoto discloses “remarkably improved” properties of the agents. One of ordinary skill in the art would know that further improvement of the dissolution rate (and subsequently the bioavailability of the drug) can be achieved by modifying the particle size of the granulation. One of ordinary skill in the art can increase the dissolution rate by reducing the particle size of the granulation. The desired dissolution rate is a problem that one of ordinary skill in the art can address by modifying the particle size of the granules.

Regarding the Declaration filed by inventor Poul Bertelsen, Applicant argues that the results from the testing of Nemoto do not predict the results from the testing method required by the claims. Applicant argues that the deficiency in the teachings of Nemoto to make a composition that has the claimed properties is not disclosed in the Advisory Action.

This is not persuasive because one of ordinary skill in the art would make the composition of Nemoto, modify the particle size of the granules and test the dissolution of the granules in dissolution medium that simulates gastric pH. One of ordinary skill in the art would know that artificial gastric juice has a pH of approximately 1.2 and that using a 0.07N HCl acid solution will also lead to a pH that simulates the gastric juices. Upon testing of the dissolution rate of the granules, one of ordinary skill in the art would modify the particle size of the granules based on the desired dissolution rate (evidenced by the teachings of Melia, Klioze and Bhardwaj above).

Applicant argues (see Page 18) that Nemoto teaches against compositions that prevent good granulation. Applicant argues that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification and that there can be no suggestion or motivation to modify the reference to exclude the formation of granules.

This is not persuasive because the proposed modification of Nemoto involves modification of the particle size of the granules based on the desired dissolution rate. This modification will not render the invention of Nemoto unsatisfactory for its intended

purpose. The modification of the granule particle size will lead to the desired dissolution rate. This is evidenced by the teachings of Melia, Klioze and Bhardwaj (stated above).

Applicant argues (see Page 19) that it is clear from the teachings of Leiberman that smaller is not always better and that granulation, the generation of larger particles, is necessary to provide powders with desirable properties for manufacturing solid dosage forms.

This is not persuasive because the incorporation of granules with a particle size from about 200 to about 400 microns (which includes the instantly claimed limitation of a mean particle size of at the most 250 micrometers) is demonstrated by Bhardwaj (Col. 6, claim 1, lines 11-24 and claim 5, lines 35-37).

Applicant asserts that the reliance on common knowledge is inappropriate in a final rejection, and moreover, the "common knowledge" asserted was contrary to a reference in the case. Applicant requests that the Examiner provide a reference relating to manufacturing of pharmaceutical compositions for oral administration demonstrating that in the size range of particles claimed, mean particle size of about 250 micrometers that one of skill in the art would know that smaller granules would allow production of oral compositions with a faster dissolution rate. Applicant submits that based on the teachings of Nemoto, one would not be motivated to make the instantly claimed compositions having a small particle size.

Please see the teachings of Bhardwaj, (Col. 6, claim 1, lines 11-24 and claim 5, lines 35-37).

The rejection of 03/11/08 is withdrawn.

In light of the supporting evidence provided by Melia, Klioze and Bhardwaj, new grounds of rejection follow.

7. Applicant's arguments, see Pages 20-21, filed 09/15/08, with respect to the rejection of claims 87-90 and 93-94 under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Penkler et al. (US 5,854,226) have been fully considered.

Applicant argues that the '226 patent provides no suggestion which would cause one skilled in the art to modify the teachings of Nemoto to use a particulate composition used in the manufacture of the composition pass through a 180 μM sieve or have a mean particle size of at most 250 μM.

Penkler is used as a supporting reference to provide the teaching of lornoxicam as an active ingredient (and an alkaline earth metal bicarbonate). Penkler is combined with Nemoto.

The rejection of 03/11/08 is withdrawn.

In light of the supporting evidence provided by Melia, Klioze and Bhardwaj, new grounds of rejection follow.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 68, 70-72, 75-80, 82-83, 85-86, 91-92, 95-96 and 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316) and Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525).

The claimed invention is a quick release pharmaceutical composition for oral administration comprising a therapeutically and/or prophylactically active substance which has a solubility of at the most 0.1% w/v in 0.1 N hydrochloric acid at room temperature, the composition being in the form of a particulate composition or being based on a particulate composition, wherein either the particles of the particulate composition used in the manufacture of the composition have a mean particle size of the most 250 micrometers, or at least 50% w/w of the particles of the particulate composition used in the manufacture of the composition pass through a 180 micrometer sieve; wherein the quick release pharmaceutical composition contains the active substance in contact with an alkaline substance; and the composition, when tested in accordance with the dissolution method I defined herein employing 0.07N hydrochloric acid as dissolution medium, releases at least 50% w/w of the active substance within the first 20 minutes of the test.

Nemoto teaches “an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs” (Page 1, claim 1). Sodium hydrogen carbonate is disclosed as the antacid (Page 1, claim 3). The antacid “accelerates the absorption of oxicam antiinflammatory drugs” (Page 2). Granules of the antacid and oxicam antiinflammatory drug are disclosed (Page 3). The

granules are formed in a mixture of alcohol and purified water (Page 4). Capsules and tablets are manufactured by adding a lubricant to the granules (Page 4). The solubility of the prepared tablets in artificial gastric juice was greater than 50% within 20 minutes of the test (Page 9, Table 3).

Nemoto does not expressly teach a mean particle size of the most 250 micrometers of the granules.

Bhardwaj et al. (US 5,578,316) teach a pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns (Col. 6, claim 1, lines 11-24). A chewable tablet containing the pharmaceutical granule composition is also disclosed (Col. 6, claim 5, lines 35-37).

Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) teach that drug particle size is a characteristic that influences dissolution from tablets and capsules (Page 515). Melia teaches that "increasing the available surface area by reducing the particle size can often markedly improve dissolution rates and lead to dramatic improvements in bioavailability" (Page 515, 1st full paragraph, under the heading "Drug particle size").

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs, as suggested by Nemoto, combine it with the pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns, as taught by Bhardwaj, and produce the instant invention.

One of ordinary skill in the art would do this because an orally administrable tablet composition that releases the active rapidly (a chewable tablet that disintegrates in the mouth will rapidly release the granules that are in the tablet) produced by using a granule composition where the final particle size of the granule is from about 200 to about 400 microns is known in the art, as evidenced by Bhardwaj. The particle size range of the granule taught by Bhardwaj renders the instant claims with the limitation of the mean particle size of the particles of the particulate composition at the most 250μm obvious to one of ordinary skill in the art. Furthermore, one of ordinary skill in the art would know that by modifying the drug particle size, i.e. by reducing the drug particle size, the surface area is increased and consequently, the dissolution rate is increased, which further leads to improved bioavailability, as evidenced by Melia.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 68 and 70, the limitation of the active substance would have been obvious over the oxicams taught by Nemoto (Page 1, claim 1). The limitation of the active substance in contact with the alkaline substance and the limitation of a particulate composition would have been obvious over the granules of antacid and oxicam disclosed by Nemoto (Page 3). The limitation of the dissolution method employing 0.07N HCl acid as dissolution medium would have been obvious over the

artificial gastric juice (with an acidic pH) taught by Nemoto (Page 9, Table 3). The limitation of the mean particle size of at the most 250 micrometers would have been obvious over the granules of antacid and oxicam disclosed by Nemoto (Page 3) in view of the final particle size of granules from about 200 to about 400 microns, as taught by Bhardwaj (Col. 6, claim 1, lines 11-24).

Regarding instant claim 71, the limitation of at least 55% w/w release would have been obvious over the solubility of preparations 3-9 as disclosed by Nemoto (Page 9, Table 3).

Regarding instant claim 72, the solubility of the active substance would have been obvious over the oxicam actives taught by Nemoto (Page 1, claim 1).

Regarding instant claims 75-79, the limitation of an excipient would have been obvious over the calcium hydrogen phosphate taught by Nemoto (Page 6, Embodiment 9).

Regarding instant claim 80, the limitation of the particle size of the filler would have been obvious over the calcium hydrogen phosphate taught by Nemoto (Page 6, Embodiment 9). One with ordinary skill in the art would modify the particle size of the filler during the process of routine optimization and the recited particle size (140 μm) would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claims 82-83, 95-96 and 108, the antacid would have been obvious over the sodium hydrogen carbonate and calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitation of the mean particle size of the

antacid-like substance would have been obvious because one with ordinary skill in the art would vary the particle size of the antacid during the process of routine experimentation depending on the desired attributes of the composition and over the final particle size of granules from about 200 to about 400 microns, as taught by Bhardwaj (Col. 6, claim 1, lines 11-24). The recited particle size (at the most 297 μm) would have been an obvious variant unless there is evidence of criticality or unexpected results.

Regarding instant claims 85-86, the active substance would have been obvious over the piroxicam and tenoxicam disclosed by Nemoto (Page 2, 3rd paragraph).

Regarding instant claims 91-92, the dosage of the active substance would have been obvious over the 2mg of chlortenoxicam and tenoxicam disclosed by Nemoto (Page 5, Table 1).

Regarding instant claim 109, the dissolution test would have would have been obvious over the artificial gastric juice (with an acidic pH) taught by Nemoto (Page 9, Table 3). A person skilled in the art would have found it obvious to test the dissolution/release of the active at various pH levels (especially acidic pH levels which are present in gastric conditions) during the process of routine optimization to ensure the release of the active ingredient.

Regarding instant claim 111, the coated tablet would have been obvious over the coating of tablets taught by Nemoto (Page 4, 2nd full paragraph).

10. Claims 87-90, 93-94 and 115-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Penkler et al. (US 5,854,226).

The teachings of Nemoto, Bhardwaj and Melia are stated above.

Nemoto, Bhardwaj and Melia do not expressly teach lornoxicam as the active substance.

Penkler teaches a pharmaceutical composition for oral administration comprising an inclusion complex of a non-steroidal anti-inflammatory drug, including lornoxicam (Col. 5, lines 66-67), an alkaline earth metal bicarbonate, and further active ingredients (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an oral solid preparation containing one or more types of antacids that accelerates the absorption of oxicam antiinflammatory drugs, as suggested by Nemoto, combine it with the pharmaceutical granule composition for oral administration where the final particle size of the granule is from about 200 to about 400 microns, as taught by Bhardwaj, further combine it with a lornoxicam and alkaline earth metal bicarbonate containing composition, as suggested by Penkler, and produce the instant invention.

One of ordinary skill in the art would do this because the use of lornoxicam in a pharmaceutical composition with an alkaline earth metal bicarbonate is known, as evidenced by Nemoto and Penkler. One with ordinary skill in the art would find it

obvious to substitute lornoxicam for the oxicams used by Nemoto during the process of routine experimentation with a reasonable expectation of success in producing a functional pharmaceutical composition comprising lornoxicam and an alkaline earth metal bicarbonate.

Regarding instant claim 87, the limitation of the lornoxicam would have been obvious over the lornoxicam taught by Penkler (Col. 5, lines 66-67).

Regarding instant claims 88-90, the further active drug substance would have been obvious over the further active drug substance, including paracetamol as taught by Penkler (Col. 8, lines 9-12).

Regarding instant claim 93, the dosage of the active substance would have been obvious over the unit compositions of lornoxicam (4mg) taught by Penkler (Figure 2). One with ordinary skill in the art would vary the dosage of the active ingredient, lornoxicam, in order to optimize the release/dissolution profile, and stability.

Regarding instant claim 94, the water content limitation would have been obvious over the drying step (after the addition of water and mixing steps) as taught by Penkler (Col. 4, line 9). A person skilled in the art would reduce the water content of the composition in order to improve shelf life and minimize interactions and leaching, therefore, the water content limitation would have been an obvious variant found during routine optimization.

Regarding new claims 115-118, the limitation of lornoxicam would have been obvious over the lornoxicam taught by Penkler (Col. 5, lines 66-67). The limitation of sodium hydrogen carbonate would have been obvious over the sodium hydrogen

carbonate disclosed by Nemoto (Page 1, claim 3). The limitation of microcrystalline cellulose would have been obvious over the microcrystalline cellulose disclosed by Nemoto (Page 5, Table 1). The limitation of calcium hydrogen phosphate anhydrous would have been obvious over the calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitations of L-HPC and hydroxy propyl cellulose would have been obvious over the low substituted hydroxypropyl cellulose and the hydroxypropyl cellulose disclosed by Nemoto (Page 5, Table 1). The limitations of water and ethanol would have been obvious over the mixture of alcohol and purified water disclosed by Nemoto (Page 4, lines 5-6). The limitation of calcium stearate would have been obvious over the calcium stearate disclosed by Nemoto (Page 4, line 12).

Regarding new claims 119-120, the limitation of the composition having mechanical strength to enable the composition to be coated using traditional coating equipment would have been obvious over the coating of tablets taught by Nemoto (Page 4, 2nd full paragraph).

11. Claims 121-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto et al. (JP 03-240729) in view of Bhardwaj et al. (US 5,578,316), Melia et al. (Aliment. Pharmacol. Therap. (1989) 3, 513-525) and Olinger et al. (US 5,651,988).

The teachings of Nemoto, Bhardwaj and Melia are stated above.

Nemoto, Bhardwaj and Melia do not expressly teach the crushing strength of the tablets of at least about 50N.

Olinger teaches that the tablet hardness or crushing strength of chewable tablets must be greater than about 30N to be commercially useful (Col. 3, lines 25-35).

Regarding new claims 121-122, the limitation of the composition further comprising a filler having binding properties would have been obvious over the calcium hydrogen phosphate disclosed by Nemoto (Page 1, claim 3). The limitation of the composition comprising the binder in the form of tablets having a diameter of 9.5mm when subjected to a crushing strength test in accordance with Ph. Eur. that has a crushing strength of at least about 50N would have been obvious over the teaching that the hardness or crushing strength of chewable tablets must be greater than about 30N to be commercially useful, as taught by Olinger (Col. 3, lines 25-35).

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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/Aradhana Sasan/ /MP WOODWARD/
Examiner, Art Unit 1615 Supervisory Patent Examiner, Art Unit 1615